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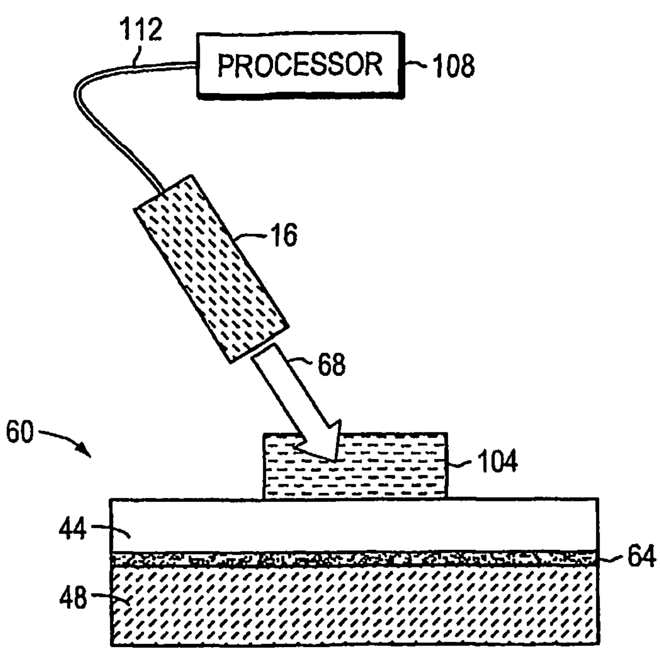
(54) Title: TREATING A DISEASED NAIL



(57) Abstract: The invention generally relates to treating diseased nails, and more particularly to treating diseased nails using radiation and/or another form of energy to substantially deactivate the source of the disease. A nail treatment can be performed by a medical professional without the use of a dying agent or an exogenous chromophore, and the treatment can be effective at eliminating the source of the disease without subjecting a patient to adverse side effects or causing substantial unwanted injury to surrounding tissue.

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Treating a Diseased Nail

BACKGROUND OF THE INVENTION

Thick, discolored, disfigured, and/or split nails can be common symptoms of disease of a fingernail or toenail. This disease can be caused by bacteria, mold, a fungus, viruses, parasites, or other organisms or microorganisms, and if left untreated, the disease can result in partial or complete destruction of a patient's nail plate.

In general, the most common type of nail disease is onychomycosis, which can be caused by a fungus, such as, a dermatophyte that can invade the nail plate and nail bed forming a patient's nail. Creams, ointments, oral medications, and radiation can be used to treat onychomycosis or other nail diseases. These treatments, however, may not eliminate the source of the disease, do not work for many patients, and can cause numerous side effects in patients.

SUMMARY OF THE INVENTION

The invention, in various embodiments, features a method and apparatus to treat a diseased nail using radiation and/or another form of energy. A treatment can eliminate or substantially eliminate the source of disease in the nail. An organism causing the disease can be deactivated. In one embodiment, the organism is thermally deactivated by delivering energy or radiation to a target area, which can be adjacent the organism or can include the organism. Tissue surrounding the organism itself can absorb radiation and transfer thermal energy to the organism to deactivate the organism, and/or the organism can absorb directly the radiation. Deactivation of the organism can render it unable to grow, reproduce and/or replicate, and, in some embodiments, can destroy the organism. Deactivation can result from thermal destruction of the organism, from denaturing or partially denaturing one or more molecules forming the organism, from initiating a

photobiological or photochemical reaction that attacks the organism, and/or from inducing an immune response that attacks the organism.

A nail treatment can be performed by a medical professional without the use of a dying agent or an exogenous chromophore, and can be effective at eliminating the source of the disease without subjecting a patient to adverse side effects. Examples of organisms causing disease in a nail that can be treated include, but are not limited to, bacteria, mold, fungi, viruses, parasites, other microorganisms, and any combination thereof. The organism can be a dermatophyte, such as, for example, epidermophyoton floccosum, trichophyton rubrum, or trichophyton mentagrophyte.

In one aspect, the invention features an apparatus for treating a diseased nail. The apparatus includes a source generating a beam of radiation having a wavelength exceeding about 400 nm, and a delivery system coupled to the source. The delivery system directs the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of a nail bed and a nail plate.

In another aspect, the invention features an apparatus for thermally deactivating an unwanted organism in a region of a diseased nail. The apparatus includes means for delivering to a target area a beam of radiation having a wavelength exceeding about 400 nm and means for causing the temperature of the target area to be raised to a level sufficient to substantially deactivate an unwanted organism in the diseased nail without causing substantial unwanted injury to surrounding tissue.

In yet another aspect, the invention features an apparatus for treating a diseased nail. The apparatus includes an energy source, and a system for delivering a beam of radiation provided by the energy source to a target area. An unwanted organism in a nail bed and/or a nail plate is thermally deactivated without causing substantial unwanted injury to the nail bed and/or the nail plate of the diseased nail. The apparatus also includes a device to deliver the beam of radiation to the diseased nail during treatment. A cooling pad can be positioned under the appendage during treatment.

In another aspect, the invention features an apparatus including a source generating a beam of radiation having a wavelength exceeding about 400 nm and a housing enclosing the source. The housing includes an aperture to transmit the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of a nail bed and a nail plate of a diseased nail.

In still another aspect, the invention features a kit for improving the cosmetic appearance of a diseased nail including a nail bed and a nail plate. The kit includes a source generating a beam of radiation having a wavelength exceeding about 400 nm and instruction means. The instruction means include instructions for directing the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of the nail bed and the nail plate. The instruction means can prescribe a wavelength, fluence, and pulse duration for treatment of the unwanted organism.

In another aspect, the invention features a method of treating a diseased nail having a nail bed and a nail plate. The method includes delivering a beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to the nail bed and/or the nail plate. The beam of radiation can have a wavelength in excess of about 400 nm.

In still another aspect, the invention features a method of treating a diseased nail having a nail bed and a nail plate. The method includes delivering a pulsed beam of radiation to a target area. The radiation absorbed is converted to thermal energy that is trapped by the nail plate of the diseased nail. An unwanted organism in at least one of the nail bed and the nail plate can be thermally deactivated without causing substantial unwanted injury to the nail bed and/or the nail plate of the diseased nail. The temperature in the region where the unwanted organism resides can be raise sufficiently to deactivate the organism, but not high enough to result in unwanted injury to the surrounding tissue.

In yet another aspect, the invention features an apparatus for treating a diseased nail having a nail bed and a nail plate. The apparatus includes means for delivering a

beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to the nail bed and/or the nail plate. The beam of radiation can have a wavelength in excess of about 400 nm.

In another aspect, the invention features a method of treating a diseased nail having a nail bed and a nail plate. The method includes delivering a beam of radiation to a target area of the diseased nail to cause the temperature of the target area to be raised to a level sufficient to substantially deactivate an unwanted organism in the diseased nail without causing substantial unwanted injury to surrounding tissue.

In yet another aspect, the invention features an apparatus for treating a diseased nail having a nail bed and a nail plate. The apparatus includes means for delivering a pulsed beam of radiation to a target area. The radiation absorbed is converted to thermal energy that is trapped by the nail plate of the diseased nail. An unwanted organism in at least one of the nail bed and the nail plate can be thermally deactivated without causing substantial unwanted injury to the nail bed and/or the nail plate of the diseased nail.

In another aspect, the invention features an apparatus for treating a diseased nail having a nail bed and nail plate. The apparatus includes means for delivering a continuous beam of radiation to a target area. The beam of radiation can be turned off when sufficient heating of the target area has been achieved.

In other examples, any of the aspects above, or any apparatus or method described herein, can include one or more of the following features. In one embodiment, the target area can be irradiated such that radiation absorbed is converted to thermal energy. The nail plate of the diseased nail can trap the thermal energy to thermally deactivate the unwanted organism present in the nail bed and/or the nail plate. In various embodiments, the beam can be delivered until occurrence of an event (e.g., a patient event such as a patient having the diseased nail indicating a sensation of pain or a predetermined event such as delivering a predetermined number of pulses)..

In some embodiments, the source can be housed in an enclosure having an aperture to transmit the beam of radiation to the target area. In certain embodiments, the

delivery system can include a fiber coupled to the source to direct the beam of radiation to the target area. In certain embodiments, the delivery system can include a light guide positioned relative to the nail plate. The light guide couples the beam of radiation to the diseased nail. A sensor can be used to determine when sufficient thermal energy has been delivered to the target area to thermally deactivate the unwanted organism. The sensor can be a photodetector (e.g., an IR detector) or a temperature sensor. A processor can be used to deactivate the source after occurrence of an event (e.g., a patient indicating a sensation of pain or delivering a predetermined number of pulses). The processor can deactivate the source in response to feedback from the sensor. For example, the sensor can sense a sufficient temperature rise in the treatment field to cause the source to be deactivated.

In certain embodiments, the delivery system can facilitate moving the pulsed beam of radiation after each pulse. In some embodiments, the source generates a second series of pulses of radiation after an interval of time to be delivered to the target area. A processor can be used to trigger the delivery system to deliver the second series of pulses of radiation to the target area after the interval of time.

In some embodiments, a pulsed beam of radiation can be used to treat the diseased nail. The pulsed beam can be moved after each pulse. Substantially all of the nail bed can be irradiated by moving the beam of radiation. In one embodiment, after an interval of time, a second series of pulses of radiation can be delivered, and the second series of pulses can irradiate substantially all of the nail bed. In various embodiments, the beam of radiation can be delivered at a rate of one pulse per second.

In one embodiment, the an immune response can be induced to at least partially deactivate the organism. In one embodiment, at least a portion of the beam of radiation is absorbed by the organism. In one embodiment, the target area includes at least one blood vessel in the nail bed. In one embodiment, the junction of the nail bed and the nail plate is selectively irradiated to treat the diseased nail. Thermal deactivation can include killing the organism.

In one embodiment, the radiation is absorbed by a target chromophore in the target area in the absence of an exogenously applied chromophore or photosensitizer. The organism can be one or more of a bacterium, a mold, a fungus, a virus, and a parasite. In one embodiment, the fungus is a dermatophyte (e.g., epidermophyton floccosum, trichophyton rubrum, and trichophyton mentagrophyte).

In various embodiments, a laser, a radio-frequency generator or a microwave generator can be used to provide the beam of radiation. The laser can be a pulsed dye laser. In some embodiments, the beam of radiation can have a wavelength between about 400 nm and about 1,100 nm (e.g., between about 585 nm and about 600 nm).

In certain embodiments, the source includes an incoherent source (e.g., an arc lamp, a flashlamp, an intense pulsed light source, a halogen lamp, or a light emitting diode array). The incoherent source can generate a beam of radiation having a wavelength between about 400 nm and about 2,000 nm.

In some embodiments, the beam of radiation can have a fluence in the range of about 4 J/cm^2 to about 10 J/cm^2. The beam of radiation can have a spotsize of between about 2 mm and about 20 mm. The pulse duration of the beam of radiation can be between 1 millisecond and 10 seconds. In some embodiments, the beam of radiation has a pulse duration equal to or less than the thermal relaxation time of the organism. A processor can determine the pulse duration based on the thermal relaxation time of the organism.

In certain embodiments, a cooling system is used to cool at least a portion of the nail plate before, during or after delivering the beam of radiation to minimize injury to the target area. In various embodiments, the an index matching solution can be introduced into a porous region of the diseased nail prior to delivering the radiation. The index matching solution can be one or more of mineral oil, glycerin, glycol, and water.

The radiation from the energy source can be scanned over an exposed surface of the disease nail during a treatment. In some embodiments, the radiation can be scanned over the exposed surface multiple times (e.g., two times, three times, four times) per

treatment. The treatment can be performed by a medical professional a single time on a diseased nail, or, in some embodiments, at least twice (e.g., two or more visits to the medical professional for treatment). One or more treatments can be followed by the application of a topical cream or an ointment to the diseased nail, the cuticle, and/or surrounding tissue or by administering a medication (e.g., oral or intravenous) to prevent reoccurrence of the unwanted organism or to eliminate the unwanted organism.

Other aspects and advantages of the invention will become apparent from the following drawings, detailed description, and claims, all of which illustrate the principles of the invention, by way of example only.

BRIEF DESCRIPTION OF THE DRAWINGS

The advantages of the invention described above, together with further advantages, may be better understood by referring to the following description taken in conjunction with the accompanying drawings. In the drawings, like reference characters generally refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1 depicts a perspective view of an exemplary apparatus for treating a diseased nail according to the invention.

FIG. 2 shows a perspective view of an exemplary apparatus for holding an appendage having a diseased nail during treatment according to the invention.

FIG. 3 shows a sectional view of another exemplary apparatus for holding an appendage having a diseased nail during treatment according to the invention.

FIG. 4 shows a sectional view of an exemplary appendage (e.g., a finger or a toe).

FIG. 5 depicts a sectional view of an exemplary nail being irradiated according to the invention.

FIG. 6 shows a sectional view of another exemplary nail being irradiated according to the invention.

FIG. 7 depicts an exemplary mechanism for improving the appearance of a diseased nail according to the invention.

FIG. 8 depicts another exemplary mechanism for improving the appearance of a diseased nail according to the invention.

FIG. 9 shows a sectional view of an exemplary nail being irradiated according to the invention.

FIG. 10 shows another sectional view of an exemplary nail being irradiated according to the invention.

FIG. 11A is a photograph of a patient's diseased fingernail prior to treatment.

FIG. 11B is a photograph of the diseased fingernail shown in FIG. 9A twenty days after a treatment according to the invention.

DESCRIPTION OF THE INVENTION

FIG. 1 shows an exemplary embodiment of a system 10 for treating a nail having a disease. The system 10 includes an energy source 12 and a delivery system 13. The energy source 12 can be housed in an enclosure having an aperture to transmit a beam of radiation to a target region to be treated. In one embodiment, a beam of radiation provided by the energy source 12 is directed via the delivery system 13 to a target region of a diseased nail having at least a nail bed and a nail plate. The target region can be a target area or a target volume of tissue. In the illustrated embodiment, the delivery system 13 includes a fiber 14 having a circular cross-section and a handpiece 16. A beam of radiation can be delivered by the fiber 14 to the handpiece 16, which can include an optical system (e.g., an optic or system of optics) to direct the beam of radiation to the target region of the diseased nail. A user can hold or manipulate the handpiece 16 to irradiate the target region. The delivery system 13 can be positioned in contact with the diseased nail, can be positioned adjacent the diseased nail, or can be positioned proximate the diseased nail. In the embodiment shown, the delivery system 13 includes a spacer 18

to space the delivery system 13 from the skin surface. In one embodiment, the spacer 18 can be a distance gauge.

In various embodiments, the energy source 12 can be an incoherent light source, a coherent light source (e.g., a laser), a microwave generator, or a radio-frequency generator. In one embodiment, the source generates ultrasonic energy that is used to treat the diseased nail. In some embodiments, two or more sources can be used together to effect a treatment. For example, an incoherent source can be used to provide a first beam of radiation while a coherent source provides a second beam of radiation. The first and second beams of radiation can share a common wavelength or can have different wavelengths. In an embodiment using an incoherent light source or a coherent light source, the beam of radiation can be a pulsed beam, a scanned beam, or a gated CW beam. The delivery system 13 can include a cooling apparatus for cooling a nail before, during, or after treatment.

In various embodiments, the beam of radiation can have a wavelength between about 250 nm and about 2,600 nm, although longer and shorter wavelengths can be used depending on the application. In some embodiments, the wavelength can be between about 400 nm and about 1,800 nm. In some embodiments, the wavelength can be between about 400 nm and about 1,100 nm. In some embodiments, the wavelength can be between about 1,160 nm and about 1,800 nm. In some embodiments, the wavelength can be between about 400 nm and about 700 nm. In one embodiment, the wavelength is between about 500 nm and about 600 nm. In one detailed embodiment, the wavelength is about 585 nm or about 600 nm. One or more of the wavelengths used can be within a range of wavelengths that are transmitted by the nail plate of the diseased nail.

Exemplary lasers include, but are not limited to, pulsed dye lasers, Nd:YAG lasers, frequency doubled Nd:YAG lasers, Nd:glass lasers, copper vapor lasers, alexandrite lasers, frequency doubled alexandrite lasers, titanium sapphire lasers, ruby lasers, fiber lasers, and diode lasers. Exemplary pulsed dye lasers include V-Beam brand lasers and C-Beam brand lasers, both of which are available from Candela Corporation

(Wayland, MA). Exemplary incoherent light sources include, but are not limited to, intense pulsed light sources, arc lamps, halogen lamps (e.g., tungsten), flashlamps (e.g., an argon or xenon lamp), and light emitting diode arrays. An incoherent light source can include one or more filters to cutoff undesired wavelengths. For example, an ultra-violet filter (e.g., a filter that cuts off wavelengths less than about 350 nm) and/or a red or infra-red filter (e.g., a filter that cuts off wavelengths greater than about 700 nm) can be used together with an incoherent light source to provide a beam of radiation to treat a nail. An exemplary incoherent light source is an Ellipse system available from Danish Dermatologic Development A/S (Denmark).

In various embodiments, the beam of radiation can have a fluence between about 1 J/cm^2 and about 50 J/cm^2, although higher and lower fluences can be used depending on the application. In some embodiments, the fluence can be between about 2 J/cm^2 and about 20 J/cm^2. In one embodiment, the fluence is between about 4 J/cm^2 and about 10 J/cm^2.

In various embodiments, the beam of radiation can have a spotsize between about 1 mm and about 25 mm, although larger and smaller spotsizes can be used depending on the application. In some embodiments, the spotsize can be between about 2 mm and about 20 mm. In one detailed embodiment, the spotsize is 7 mm.

In various embodiments, the beam of radiation can have a pulsewidth between about 10 μs and about 30 s, although larger and smaller pulsewidths can be used depending on the application. In some embodiments, the pulsewidth can be between about 100 μs and about 1 s. In one detailed embodiment, the pulsewidth can be about 100 μs, about 500 μs, about 1 ms, about 5 ms, about 10 ms, about 50 ms, about 100 ms, about 500 ms, or about 1 s.

In various embodiments, the beam of radiation can be delivered at a rate of between about 0.1 pulse per second and about 10 pulses per second, although faster and slower pulse rates can be used depending on the application. In one detailed embodiment, the pulse rate is about 1 pulse per second.

FIG. 2 shows an exemplary apparatus **20** for positioning a patient's appendage **24** (e.g., a finger or a toe) having a diseased nail **26**. The apparatus **20** includes a base **28** defining an opening **32** for retaining or cradling the appendage **24** during a treatment. FIG. 3 shows an exemplary embodiment of an apparatus **20'** including a cooling pad **36**. Cooling can facilitate a treatment and can reduce a patient's sensitivity to pain. The cooling pad **36** can be placed below the appendage **24**, or can be affixed to the base **28** to cool the appendage **24**. The cooling pad **36** can be filled with ice, a frozen gel pack, or a cooling fluid. In one embodiment, a system for treating a diseased nail **26** includes an energy source **12**, a delivery system **13** for applying energy to the appendage **24** having the diseased nail **26**, and an apparatus **20** for positioning the appendage during treatment.

To minimize thermal injury to tissue surrounding the diseased nail **26**, the delivery system **13** shown in FIG. 1 can include a cooling system for cooling the nail plate before, during or after delivery of radiation. Cooling can include contact conduction cooling, evaporative spray cooling, convective air flow cooling, or a combination of the aforementioned. In one embodiment, the handpiece **16** includes a nail contacting portion that can be brought into contact with the region of the diseased nail receiving the beam of radiation. The nail contacting portion can cool the nail plate. The nail contacting portion can include a sapphire or glass window and a fluid passage containing a cooling fluid. The cooling fluid can be a fluorocarbon type cooling fluid, which can be transparent to the radiation used. The cooling fluid can circulate through the fluid passage and past the window contacting the nail plate.

A spray cooling device can use cryogen, water, or air as a coolant. In one embodiment, a dynamic cooling device can be used to cool the nail plate and/or surrounding tissue (e.g., a DCD available from Candela Corporation). For example, the delivery system **13** shown in FIG. 1 can include tubing for delivering a cooling fluid to the handpiece **16**. The tubing can be connected to a container of a cold fluid, and the handpiece can include a valve for delivering a spurt of cold fluid to the nail plate. Heat can be extracted from the nail plate by virtue of evaporative cooling of the cold fluid. The

fluid can be a non-toxic substance with high vapor pressure at normal body temperature, such as a Freon or tetrafluoroethane.

FIG. 4 shows a sectional view of an appendage **40** (e.g., a finger or a toe) including a nail plate **44**, a nail bed **48**, and nail root **52**. The nail plate **44** can be formed from a number of horny plates extending from the nail root **52** and cuticle **56**. The nail **44** is positioned over and protects the nail bed **48**. One or more organisms can invade or permeate the nail plate **44**, the nail bed **48**, the nail root **52**, or the nail matrix to cause an infection or disease in the nail.

FIG. 5 depicts irradiation of a section of an exemplary nail **60** having the nail plate **44**, the nail bed **48**, and an unwanted organism causing disease **64** in the nail **60**. A beam of radiation **68** is applied to a target area of the nail **60**. The target area can be a portion of the nail plate **44**, a portion of the nail bed **48**, a portion of the disease **64**, the unwanted organism itself, or any combination thereof. Chromophores in the nail plate **44** and nail bed **48** can include, but are not limited to, a blood vessel, a wall of a blood vessel, melanin, water, collagen, a blood cell, hemoglobin, plasma, the disease causing organism, or any combination thereof. Energy from the beam of radiation **68** can be absorbed by the target area and converted to thermal energy to deactivate the unwanted organism. The beam of radiation **68** can deactivate the unwanted organism without causing unwanted injury or substantial permanent injury to the nail plate **44** and/or the nail bed **48**. In various embodiments, energy can be delivered at a predetermined wavelength, a predetermined pulsewidth, and a predetermined energy or fluence.

The unwanted organism can live and breed in and/or around the area of the junction between the nail plate **44** and the nail bed **48**. The organism can get its nutrition from the nail plate **44** and can get moisture from the nail bed **48** to sustain itself. In some embodiments, to effectively treat the nail disease, energy can be directed selectively to a target area proximate to a bottom portion of the nail plate **44** and a top portion of the nail bed **48** to deactivate the unwanted organism. In one embodiment, the unwanted organism

is thermally deactivated as the target area absorbs the beam of radiation and transfer the thermal energy to the unwanted organism.

In various embodiments, the beam of radiation can be selected to pass through the nail plate **44** and to be absorbed by the nail bed **48** (e.g., a top portion of the nail bed) and/or the unwanted organism. For example, the beam of radiation can be transmitted or substantially transmitted through the nail plate **44** to avoid heating the nail plate **44** as a whole. When the nail plate is heated as a whole, it can remain hot for an extended period of time, which can lead to unwanted injury to the surrounding tissue. Tissue injury depends not only on temperature, but also on the length of time at an elevated temperature. By selectively depositing energy to the nail plate **44**, the nail bed **48**, and/or the junction region therebetween, one can maximize the injury to the disease causing organism while minimizing injury to the surrounding tissue. In various embodiments, the tissue can be heated to a temperature of between about 50° C and about 80° C, although higher and lower temperatures can be used depending on the application. In one embodiment, the temperature is between about 55° C and about 70° C.

In some embodiments, a pulsed light source is used to selectively deliver the beam of radiation to a target area including the nail bed **48** and/or the unwanted organism. This can result in the temperature in the junction region between the nail plate **44** and the nail bed **48** being increased to thermally deactivate the unwanted organism without causing substantial unwanted injury or substantial permanent injury to surrounding tissue. In various embodiments, the radiation can also deactivate the unwanted organism by denaturing or partially denaturing one or more molecules forming the unwanted organism, by initiating a photobiological or photochemical reaction that attacks the organism, and/or by inducing an immune response that attacks the organism. In some embodiments, one or more of these mechanisms is induced by the beam of radiation to treat the diseased nail.

In various embodiments, the pulsed beam of radiation is scanned over the surface of the disease nail during a treatment. That is, the beam of radiation can be moved after delivery of one or more pulses. In one embodiment, the beam of radiation is moved after

a single pulse. The pulse rate can be one pulse per second, although other suitable pulse rates can be used. The beam of radiation can be moved until the entire surface of the diseased nail has been substantially completely irradiated.

Referring to FIG. 5, the beam of radiation **68** is applied to a first position. The beam of radiation can be moved to at least a second position **72**, a third position **76**, and a fourth position **80**. The beam can be moved in a linear fashion, in a predetermined pattern, or in a random fashion across the surface of the diseased nail. In some embodiments, the radiation can be scanned over the surface of the diseased nail multiple times during a treatment. The radiation can be scanned until the occurrence of an event, such as, for example, a patient indicating a sensation of pain, reaching a predetermined number of cycles of treatment, or reaching a predetermined number of pulses of radiation. In addition, treatment can be performed a single time, or multiple times over a course of hours, days, weeks, or months.

One or more treatments can be followed by the application of a topical cream or an ointment to the diseased nail, the cuticle, and/or surrounding tissue or by administering a medication (e.g., oral or intravenous) to prevent reoccurrence of the unwanted organism or to eliminate the unwanted organism. In one embodiment, a diseased nail can be scraped to remove excess growth prior to applying energy to the diseased nail.

FIG. 6 shows another exemplary embodiment of irradiation of a section of the exemplary nail **60**. According to the illustrated embodiment, the beams of radiation **68**, **72**, **76**, and **80** applied to the target area are absorbed by the nail bed **48** and/or the unwanted organism. The energy is converted to thermal energy **84** that is trapped by the nail plate **44**. The unwanted organism is not destroyed directly by the radiation; instead, thermal energy **84** trapped by the nail plate **44** deactivates the unwanted organism to treat the diseased nail **60**. As the beam of radiation is scanned across the surface of the diseased nail, e.g., over a period of seconds, the temperature of the nail bed **48** can increase until the temperature is high enough that the patient starts to feel pain or until a predetermined number of pulses is delivered. The temperature of the junction region near

the top of the nail bed **48** and bottom of the nail plate **44** can reach a level at which the unwanted organism can be deactivated without causing substantial unwanted injury or substantial permanent injury to surrounding tissue.

FIG. **7** shows an exemplary mechanism for improving the appearance of a diseased nail. An appendage **88** (e.g., a finger or a toe) includes a nail having a diseased portion **92** affected by an unwanted organism. After a single treatment or after series of treatments, at least a portion of the unwanted organism can be deactivated, and healthy nail **96** can push the diseased portion **92** out as the nail grows out. If the unwanted organism is substantially deactivated such that the disease state can not reoccur, the nail eventually can return to a substantially healthy state **100** free of disease. The diseased portion **92** can be cut or scraped as the nail grows out to facilitate removal of the diseased portion and/or the unwanted organism.

FIG. **8** shows another exemplary mechanism for improving the appearance of a diseased nail. The appendage **88** (e.g., a finger or a toe) includes a nail having the diseased portion **92** affected by an unwanted organism. After a single treatment or after series of treatments, at least a portion of the unwanted organism can be deactivated, and the discoloration of the diseased portion **92'** can lighten. If the unwanted organism is substantially deactivated such that the disease state can not reoccur, new nail growth can return the nail to a substantially healthy state **100** free of disease. The diseased portion **92** or **92'** can be cut or scraped as the nail grows out to facilitate removal of the diseased portion and/or the unwanted organism.

In one embodiment, one or more holes can be drilled into the nail plate **44** prior to delivering the beam of radiation **68**. A hole can facilitate delivery of the beam of radiation to the nail bed **48** by removing an unwanted absorber such as the nail plate **44** or the disease itself. A hole also can facilitate delivery of a dying agent or a chromophore to the nail plate **44** or the nail bed **48**, can allow heat to diffuse from the nail bed **48** during a treatment, and can facilitate cooling of the nail plate **44** by increasing nail surface to air contact.

In one embodiment, the predetermined wavelength can be selected by obtaining a sample of a diseased nail (e.g., a nail scraping or clipping) and examining the sample, or a culture grown from the sample, under a microscope to determine the source of the disease. In one embodiment, a spectroscopic measurement of the diseased nail is made to determine the absorption spectrum of the cultured organism. Once the unwanted organism is identified, a wavelength corresponding to an absorption peak for that organism can be selected. For example, if the source of the infection is a bacterium that absorbs light having a wavelength in a range of about 500 nm to about 600 nm, a light source having a suitable wavelength can be used to eliminate the bacterium. In addition, the wavelength region can be selected by avoiding a region where healthy tissue surrounding the diseased nail has a strong absorption feature. In one detailed embodiment, a wavelength is selected where the cultured organism shows a strong absorption feature and where healthy tissue surrounding the diseased nail shows a weak absorption feature.

In one embodiment, the method of selecting a predetermined wavelength is based on treating one or more of the typical sources of infection. For example, three of the most common fungi (e.g., dermatophytes) that cause nail disease are epidermophyton floccosum, trichophyton rubrum, and trichophyton metagrophytes. Each of these dermatophytes are orange to brown in color. For example, when grown in a Petri dish, epidermophyton floccosum colonies are a brownish-orange on the bottom of the colony and a brownish-yellow on the top of the colony; trichophyton rubrum is blood red at the bottom of the colony and a whitish-cream on the top of the colony; and trichophyton mentagrophytes is a pale pinkish brown on the bottom of the colony and cream on the top of the colony. As a result of the orange/red/brown color of the dermatophytes responsible for the nail disease, a blue to green wavelength (e.g., about 400 nm to about 550 nm) can be selected . In some embodiments, especially embodiments in which the source of the infection has a reddish color, the wavelength selected can be within the blue to orange region (e.g., about 400 nm to about 600 nm). In certain embodiments in which injury to

the nail bed **48** and/or surrounding tissue is a concern, wavelengths that are absorbed by blood can be avoided. For example, wavelengths between about 500 nm and about 600 nm can be avoided. In some embodiments, the wavelength that is best absorbed by the organism can be between about 500 nm and about 750 nm, between about 600 nm and about 700 nm, or between about 530 nm and about 600 nm.

In one embodiment, the method of selecting a predetermined wavelength can be based on using water as an absorber. A wavelength well absorbed by water, but not well absorbed by the nail plate **44** can permit radiation to pass through the nail plate **44** and deposit energy in a top portion of the nail bed **48**. For example, a wavelength in the near to mid-infrared region can be used (e.g., about 1,400 nm, about 1,450 nm, or about 1,900 nm).

In some embodiments, the energy source includes a radio-frequency (RF) generator. RF energy can be used to produce heat within a diseased nail to deactivate the disease causing organisms. In general, tissue is resistively heated by RF energy. Healthy nail tissue, however, is formed of an insulating material, and RF energy, therefore, is not strongly absorbed. In a diseased nail, the organism causing the disease can be conductive, and provide enough conductivity to absorb the RF energy. As a result, RF energy directed to a target area of a diseased nail can preferentially heat the organism. An RF delivery system can be capacitively coupled to the nail to facilitate delivery of the RF energy. One technique to capacitively couple the RF delivery system to the nail plate includes placing a broad area probe (e.g., a broad area electrode) over a large portion of the nail plate of the diseased nail. A radio-frequency is applied that can provide sufficient current to treat the diseased nail. In some embodiments, the frequency used is greater than the frequency typically used by electrocautery devices used for heating tissue. For example, in one embodiment, the frequency used to treat the diseased nail is greater than about 50 MHz.

In some embodiments, the energy source includes a microwave generator. The microwave energy can be used to thermally deactivate the unwanted organism without causing unwanted side effects to the patient or substantial injury to the tissue surrounding

the diseased nail. In general, the beam of microwave energy can excite water molecules in the nail bed without substantially being absorbed by the nail plate.

In some embodiments, the energy source includes an ultrasound generator, which can be, for example, a high intensity ultrasound source or a high power focused ultrasound source. The ultrasonic energy can be used to thermally deactivate the unwanted organism without causing unwanted side effects to the patient or substantial unwanted or permanent injury to the tissue surrounding the diseased nail. Due to the large impedance mismatch of sound waves between a patient's relatively hard nail plate and soft nail bed tissue, ultrasonic energy devices are particularly well suited to provide selective energy deposition. As a result, ultrasonic energy devices can deliver sufficient energy to deactivate the source of the infection, while not causing substantial unwanted injury to surrounding tissue.

For example, ultrasonic energy directed to a diseased nail can be substantially reflected at the junction between the nail plate and the nail bed. As a result, the nail bed will not be as strongly heated as the nail plate by the ultrasound energy. Moreover, in general, the nail plate has a higher attenuation or absorption than the underlying nail bed. Thus, a high intensity, focused ultrasound device applied to the nail plate via a broad area probe placed over the surface of the diseased nail effectively heats up the nail plate without causing excessive thermal damage to the underlying nail bed.

In various embodiments, the pulsewidth can be selected to limit exposure and thermal damage to tissue surrounding the diseased nail. In one embodiment, the pulsewidth used is determined by the average size of the infecting organism. For example, the average particle size of the organism can be determined prior to delivering radiation to the diseased nail. In one embodiment, the size of the organism can be determined by collecting a diseased nail scraping or clipping from the patient, and examining the organism found in the scraping or clipping. The size or average size of the organism particle(s) can be measured, for example, using a microscope.

Once the average particle size is determined, a pulsewidth equal to or less than the thermal relaxation time for the organism can be used. For example, if the average particle size is about 10 μm, the pulsewidth selected can be about 0.05 ms. In general, the pulsewidth can scale as the square of the particle size. Thus, if the average particle size measured from a sample is about 100 μm, then the pulsewidth used to thermally deactivate the organism can be about 5 ms.

In some embodiments, the energy or fluence of the beam of radiation is predetermined so as to thermally destroy the particular source of the disease without causing substantial adverse side effects for the patient or substantial injury to surrounding tissue. In one embodiment, the fluence is selected after determining the source and/or size of the infection. Accordingly, the fluence can be tuned to preferentially heat the source of the disease without damaging or substantially injuring surrounding tissue.

In general, substantially all of the electromagnetic radiation within a broad wavelength range can be transmitted through a diseased nail in the early stages of infection. If an infection has progressed and the diseased nail is cloudy, yellow, or thick, a portion of the diseased nail can be scraped away, and/or an index matching solution can be applied to the diseased nail to improve its clarity. The index matching solution can be introduced to or infused in a porous region of the nail. For example, a porous nail can appear cloudy due to a difference in the index of refraction between air in the pores and the solid nail. To reduce the cloudiness and improve light transmission through the nail, the index matching solution can be applied to the nail to fill the voids, thereby decreasing the difference in the index of refraction. In general, index matching solutions are transparent fluids, such as, for example, water, glycol (e.g., ethylene glycol), glycerin, and mineral oil.

In one embodiment, an oral medication can be ingested and/or a topical ointment or cream can be applied to the diseased nail before, during, or after treatment with a beam radiation. For, example, after radiation treatment, a topical, such as, for example, potassium permanganate, ciclopirox olamine, an azole, or an organic acid can be applied

to the treated nail. One or more additional rounds of the topical can be applied at a later time (e.g., the next day, the next week, or one or more months). In addition, one or more rounds of radiation treatment can be performed to the diseased nail to ensure that the source of the infection is thermally destroyed. Alternatively or in addition , a medication, such as an oral or intravenous medication, can be administered before, during, or after a schedule of radiation treatments. In some embodiments, portions of an appendage that do not require irradiation can be masked off to avoid unwanted exposure to radiation.

In one detailed embodiment, a treatment is performed using a pulsed, coherent beam of radiation having a laser fluence in the range of about 4 J/cm^2 to about 20 J/cm^2, a spotsize of about 7 mm, and a wavelength of about 595 nm. The fluence can be selected based on the thickness of the nail to be treated; for example, a thicker nail can require a higher fluence. After each pulse, the beam can be moved from the target area to a neighboring target area. The pulse rate can be about 1 pulse per second. Radiation can be applied to substantially the entire nail plate by incrementally moving the beam. After substantially all of the entire nail plate is irradiated, the treatment can be stopped, or the treatment can be repeated by going over the nail one or more additional times. Treatment can be terminated when the patient indicates a sensation of pain, after a predetermined number of cycles of treatment, or after a predetermined number of pulses of radiation.

In one exemplary embodiment, a diseased nail was treated over a three month period using a Candela V-Beam model dye laser having a wavelength of about 595 nm, a spotsize of about 10 mm, a pulse duration of about 20 ms, and a fluence of between about 3.5 J/cm^2 to about 4 J/cm^2, or using a Candela V-Beam model dye laser having a wavelength of about 595 nm, a spotsize of about 7 mm, a pulse duration of about 20 ms, and a fluence of about 8 J/cm^2. Each treatment consisted of moving the beam of radiation over the nail for three cycles, twice per week, for 24 total treatments. No topical medicine was applied to the nail. After one week of treatment, the diseased portion of the nail did not spread to other portions of the nail. After one month of treatment, the diseased portion of the nail had decreased in size. After two months and during the third month of

treatment, respectively, the diseased portion of the nail continued to decrease in size. After three months of treatment, the nail was substantially without disease and was substantially completely healthy.

In another exemplary embodiment, a diseased nail was treated over a three month period using a Candela V-Beam model dye laser having a wavelength of about 595 nm, a spotsize of about 10 mm, a pulse duration of about 20 ms, and a fluence of between about 3.5 J/cm^2 to about 4 J/cm^2. Each treatment consisted of passing the probe over the nail a single time, twice per week, for a total of 24 treatments. After three months of treatment, the size of the diseased portion of the fingernail was reduced, and a healthy portion of the nail was growing out to the cuticle.

FIG. 9 depicts irradiation of a section of an exemplary nail **60** having the nail plate **44**, the nail bed **48**, and an unwanted organism causing disease **64** in the nail **60**. A beam of radiation **68** is applied to a target area of the nail **60**. The target area can be a portion of the nail plate **44**, a portion of the nail bed **48**, a portion of the disease **64**, the unwanted organism itself, or any combination thereof. Although the beam of radiation is denoted by reference numeral **68**, the beam of radiation can be any beam of radiation, including, but not limited to, beams **68**, **72**, **76**, and **80**.

A delivery system **16** is used to deliver the beam of radiation **68** to the target area. In one embodiment, the delivery system **16** includes a source of the radiation. A light guide **104** is positioned relative to the nail **60** to couple the beam of radiation **68** to the nail **60**. The light guide **104** can be place proximate to the nail **60**, spaced from the nail v, and/or in contact with the nail **60**. A gel can be used to couple the light guide **104** to the nail **60**. In one embodiment, the light guide **104** couples broadband light from an incoherent source to the nail **60**.

A processor **108** can be in communication with the delivery system **16**. A cable **112** or a wireless connection can be used. The processor **108** can be used to deactivate a source of energy or the delivery system **16** after an event. The processor **108** can activate or reactivate the source of energy or the delivery system **16** after an interval of time. The

processor 108 can be used to control the delivery system **16** as the beam of radiation **68** is scanned over the nail **60**, e.g., determining the firing or sequence of pulses. For example, in one embodiment, the processor **108** triggers the delivery system **16** to deliver a second series of pulses of radiation to the target area after an interval of time. In certain embodiments, the delivery system **16** facilitates moving the beam of radiation **68**.

FIG. **10** depicts irradiation of a section of an exemplary nail **60**. A sensor **116** is used to collect a signal **120** from the target area. The sensor **116** can be a temperature sensor, such as a radiometer, or can be a photodetector (e.g., an IR detector). The signal **120** can include a thermal signature and/or an optical signal. The sensor **116** can be used to determine when sufficient thermal energy has been delivered to the target area to thermally deactivate the unwanted organism.

In one embodiment, the sensor **116** is connected to the processor **108**, which can be used to determine when sufficient thermal energy has been delivered to the target area. The processor **108** can deactivate the source of energy or the delivery system **16** based on a signal received from the sensor **116**. In one embodiment, the source of energy or the delivery system **16** can be deactivated when the temperature of the target areas achieves a temperature between about 50° C and about 70° C.

FIG. **11A** shows a diseased fingernail of a 65 year old women prior to treatment. This particular patient was in bad health and had received steroids for a month prior to beginning her treatment. As a result of her health and prior medical history, oral treatments and ointments were not an option. A culture of a nail sample indicated that the nail disease was of the hyperkeratotic form with nail matrix involvement. This patient received two to three applications (e.g., two to three cycles) of a Candela V-beam dye laser having a wavelength of about 595 nm, a spotsize of about 7 mm, a pulse duration of about 20 ms, and a fluence of about 7.5 J/cm^2. Twenty days after the first treatment, the patient came in for a second treatment. FIG. **11B** shows the diseased nail prior to the second treatment. As shown in FIG. **11B**, a healthy portion of the nail is growing out to about the region of the cuticle.

The invention features a kit suitable for use in the treatment of a diseased nail. The kit can be used to improve the cosmetic appearance of the diseased nail. The kit can include a source of a beam of radiation and instruction means. The instruction means can include instructions for directing the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of a nail bed and a nail plate. The instruction means can prescribe a wavelength, fluence, and/or pulse duration for treatment of the diseased nail and/or unwanted organism. The instruction means, e.g., treatment guidelines, can be provided in paper form, for example, as a leaflet, booklet, book, manual, or other like, or in electronic form, e.g., as a file recorded on a computer readable medium such as a drive, CD-ROM, DVD, or the like.

While the invention has been particularly shown and described with reference to specific illustrative embodiments, it should be understood that various changes in form and detail may be made without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed:

1. An apparatus comprising:

a source generating a beam of radiation having a wavelength exceeding about 400 nm; and

a delivery system coupled to the source, wherein the delivery system directs the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of a nail bed and a nail plate of a diseased nail.

2. The apparatus of claim 1 wherein the source is housed in an enclosure having an aperture to transmit the beam of radiation to the target area.

3. The apparatus of claim 1 or 2 wherein the delivery system comprises a fiber coupled to the source directing the beam of radiation to the target area.

4. The apparatus of claim of any of the preceding claims wherein the delivery system comprises a light guide positioned relative to the nail plate, the light guide coupling the beam of radiation to the diseased nail.

5. The apparatus of any of the preceding claims further comprising a sensor to determine when sufficient thermal energy has been delivered to the target area to thermally deactivate the unwanted organism.

6. The apparatus of claim 5 wherein the sensor is a temperature sensor.

7. The apparatus of claim 5 wherein the sensor is an infrared detector.

8. The apparatus of any of the preceding claims further comprising a processor to deactivate the source after occurrence of an event.

9. The apparatus of claim 8 wherein the event includes a patient having the diseased nail indicating a sensation of pain.

10. The apparatus of claim 8 wherein the event includes delivering a predetermined number of pulses.

11. The apparatus of claim 8 wherein the event includes the sensor having sensed a sufficient temperature rise in the target area.

12. The apparatus of claim 1 or 2 further comprising a processor to deactivate the source after delivering a predetermined number of pulses.

13. The apparatus of any of the preceding claims wherein the source generates a pulsed beam of radiation.

14. The apparatus of claim 13 wherein the delivery system facilitates moving the pulsed beam of radiation after each pulse.

15. The apparatus of any of the preceding claims further comprising a processor wherein the source generates a second series of pulses of radiation after an interval of time to be delivered to the target area.

16. The apparatus of claim 15 wherein a processor triggers the delivery system to deliver the second series of pulses of radiation to the target area after the interval of time.

17. The apparatus of any of the preceding claims wherein thermal deactivation comprises killing the organism.

18. The apparatus of any of the preceding claims wherein the organism comprises at least one of a bacterium, a mold, a fungus, a virus, and a parasite.

19. The apparatus of claim 18 wherein the fungus is a dermatophyte selected from the group consisting of epidermophyton floccosum, trichophyton rubrum, and trichophyton mentagrophyte.

20. The apparatus of any of the preceding claims wherein the source delivers the beam of radiation at a rate of one pulse per second.

21. The apparatus of any of the preceding claims the beam of radiation has a pulse duration of between about 1 milliseconds and about 10 seconds.

22. The apparatus of any of the preceding claims wherein the source comprises a laser.

23. The apparatus of claim 22 wherein the laser comprises a pulsed dye laser.

24. The apparatus of claim 22 or 23 wherein the laser generates a beam of radiation having a wavelength between about 400 nm and about 600 nm.

25. The apparatus of any of the preceding claims wherein the source includes an incoherent source.

26. The apparatus of claim 25 wherein the incoherent source comprises an arc lamp, a flashlamp, an intense pulsed light source, a tungsten lamp, a halogen lamp, or a light emitting diode array.

27. The apparatus of claim 25 wherein the incoherent source generates a beam of radiation having a wavelength between about 400 nm and about 2,000 nm.

28. The apparatus of any of the preceding claims wherein the beam of radiation comprises a fluence in the range of about 4 J/cm^2 to about 10 J/cm^2.

29. The apparatus of any of the preceding claims wherein the beam of radiation has a spotsize of between about 2 mm and about 20 mm.

30. The apparatus of any of the preceding claims wherein the beam of radiation comprises a pulse duration equal to or less than the thermal relaxation time of the organism.

31. The apparatus of claim 30 further comprising a processor to determine the pulse duration based on the thermal relaxation time of the organism.

32. The apparatus of any of the preceding claims further comprising a cooling system for cooling at least a portion of the nail plate before, during or after delivering the beam of radiation to minimize injury to the target area.

33. An apparatus comprising:

means for delivering to a target area a beam of radiation having a wavelength exceeding about 400 nm; and

means for causing the temperature of the target area to be raised to a level sufficient to substantially deactivate an unwanted organism in a diseased nail without causing substantial unwanted injury to surrounding tissue.

34. An apparatus comprising:

an energy source;

a system for delivering a beam of radiation provided by the energy source to a target area to thermally deactivate an unwanted organism in at least one of a nail bed and a nail plate of a diseased nail without causing substantial unwanted injury to at least one of the nail bed and the nail plate; and

a device to direct the beam of radiation to the diseased nail during treatment.

35. The apparatus of claim 34 wherein the energy source is a microwave source, a high intensity ultrasound source, or a radio frequency source.

36. The apparatus of claim 34 further comprising a cooling pad to be positioned under the appendage during treatment.

37. An apparatus comprising:

a source generating a beam of radiation having a wavelength exceeding about 400 nm; and

a housing enclosing the source, the housing including an aperture to transmit the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of a nail bed and a nail plate of a diseased nail.

38. A kit for improving the cosmetic appearance of a diseased nail including a nail bed and a nail plate, the kit comprising:

a source generating a beam of radiation having a wavelength exceeding about 400 nm; and

instruction means including instructions for directing the beam of radiation to a target area to thermally deactivate an unwanted organism without causing substantial unwanted injury to at least one of the nail bed and the nail plate.

39. The kit of claim 38 wherein the instruction means prescribe a wavelength, fluence, and pulse duration for treatment of the unwanted organism.

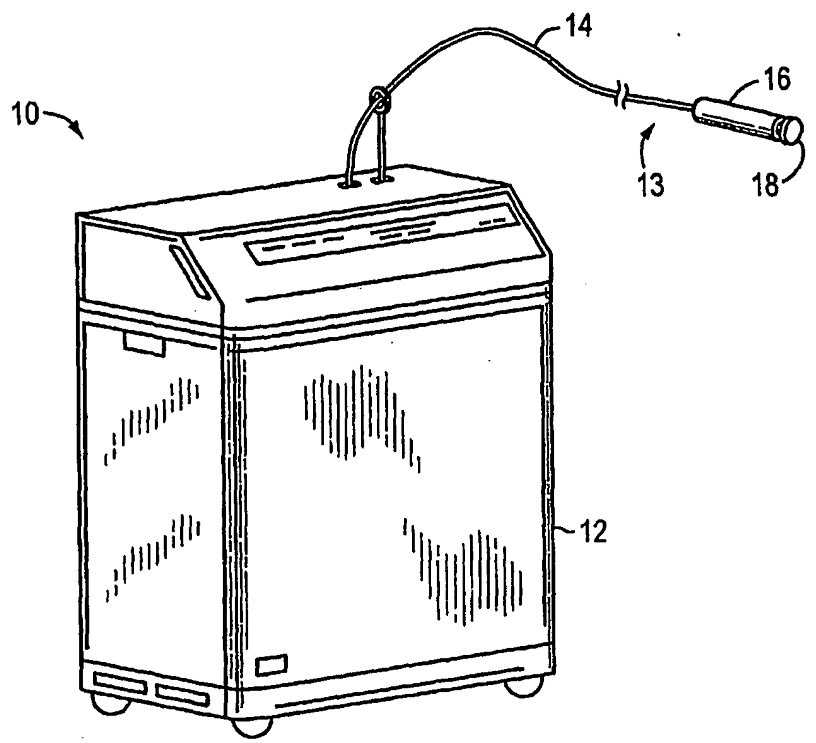

FIG. 1

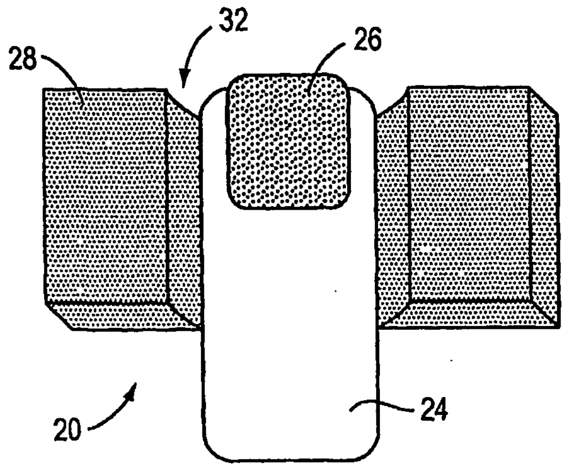

FIG. 2

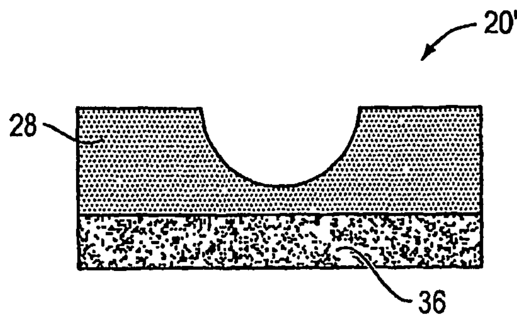

FIG. 3

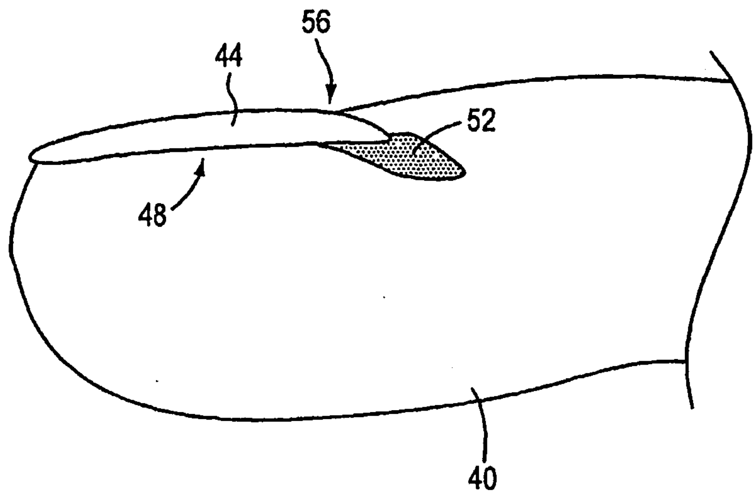

FIG. 4

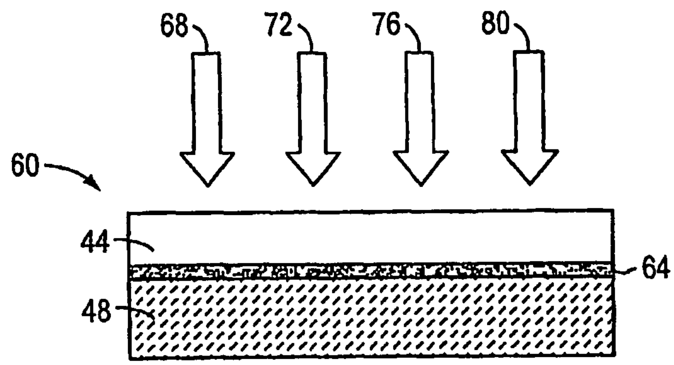

FIG. 5

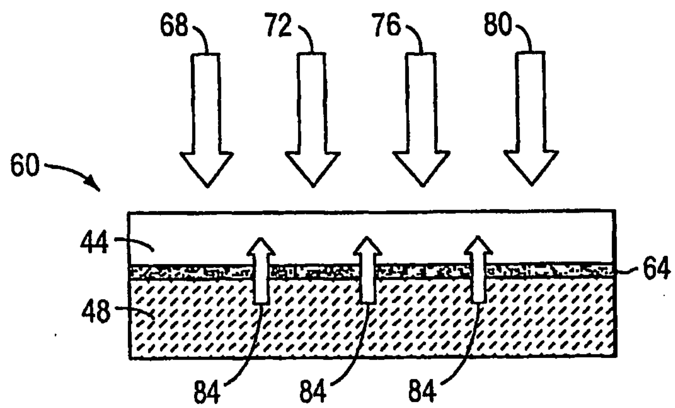

FIG. 6

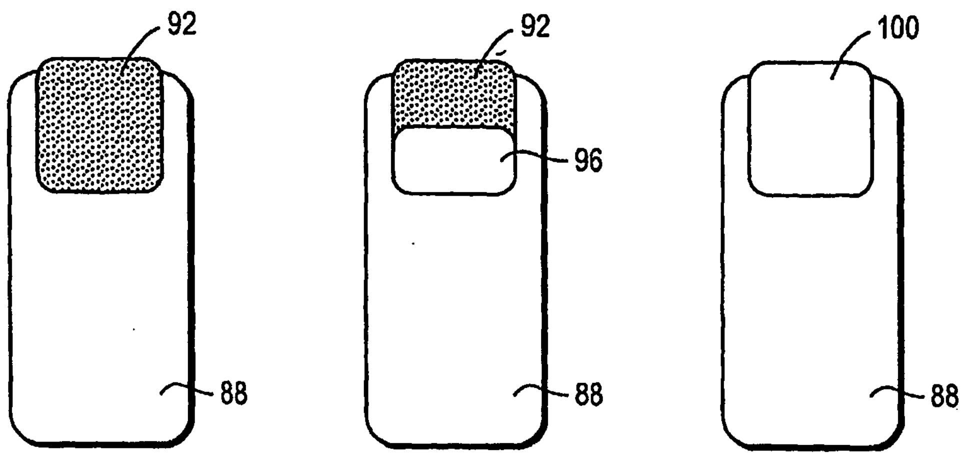

FIG. 7

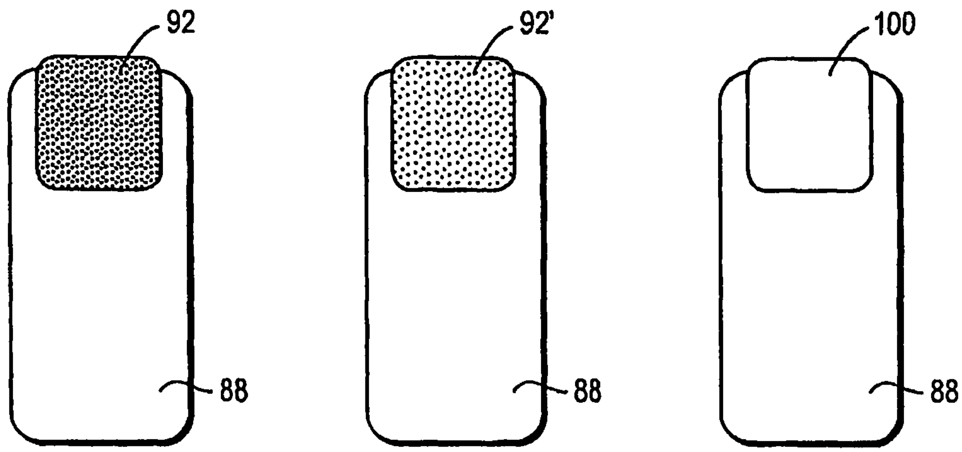

FIG. 8

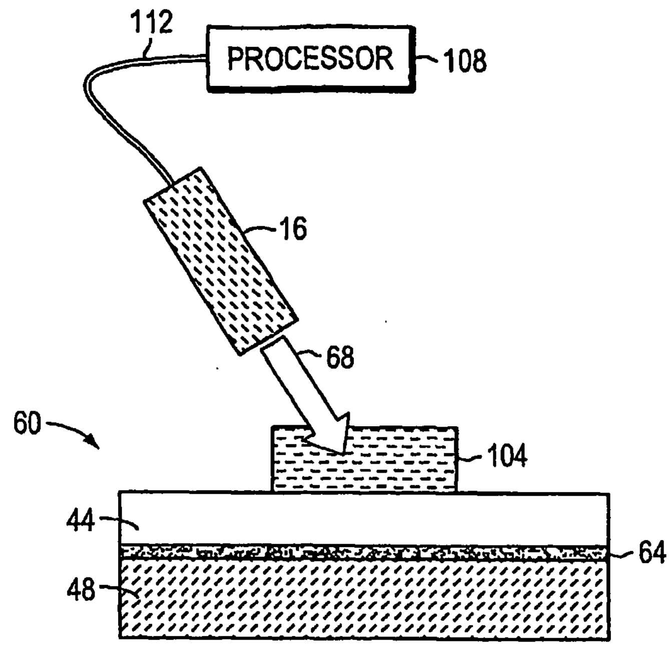

FIG. 9

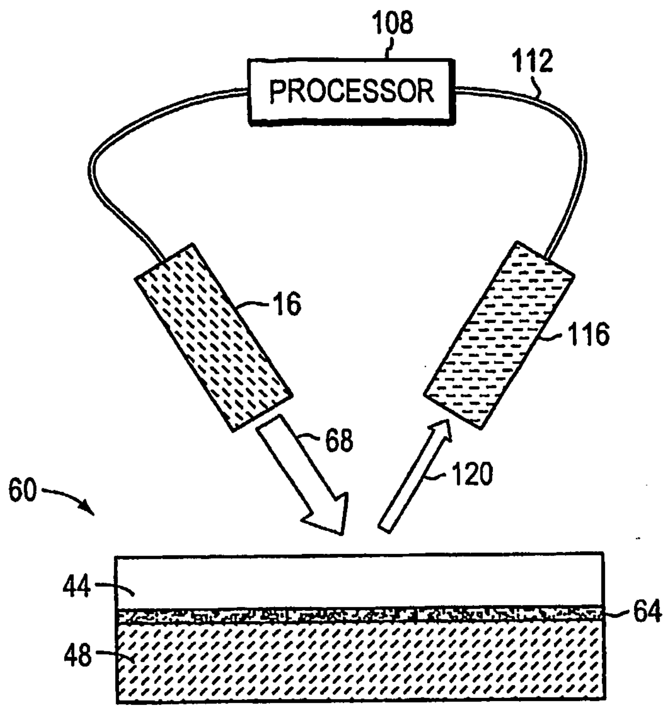

FIG. 10

FIG. 11B

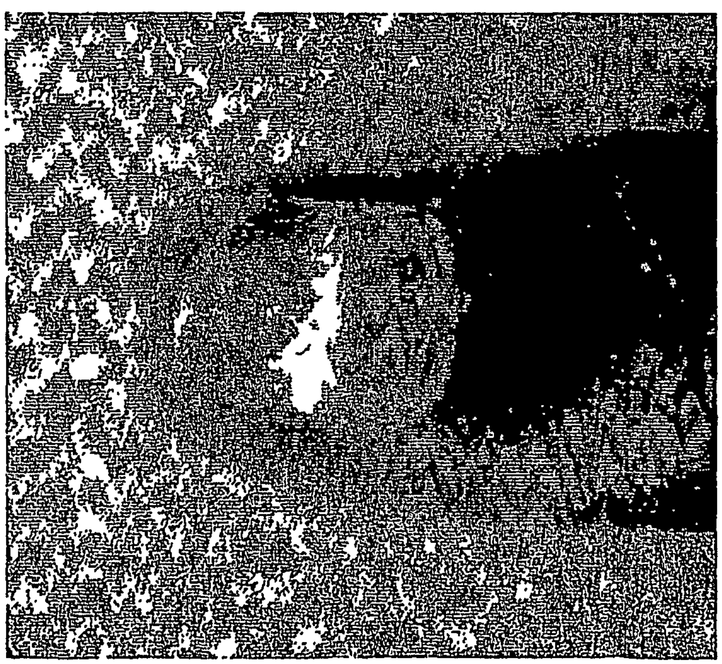

FIG. 11A